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Supporting shared decision making using an Option Grid for osteoarthritis of the knee in an interface musculoskeletal clinic: A stepped wedge trial

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ABSTRACT

Objective: To evaluate whether introducing tools, specifically designed for use in clinical encounters, namely Option Grids, into a clinical practice setting leads to higher levels of shared decision making.
Methods: A stepped wedge trial design where 6 physiotherapists at an interface clinic in Oldham, UK, were sequentially instructed in how to use an Option Grid for osteoarthritis of the knee. Patients with suspected or confirmed osteoarthritis of the knee were recruited, six per clinician prior to instruction, and six per clinician afterwards. We measured shared decision making, patient knowledge, and readiness to decide.
Results: A total of 72 patients were recruited; 36 were allocated to the intervention group. There was an 8.4 point (95% CI 4.4 to 12.2) increase in the Observer OPTION score (range 0–100) in the intervention group. The mean gain in knowledge was 0.9 points (score range 0–5, 95% CI, 0.3 to 1.5). There was no increase in encounter duration.
Conclusion: Shared decision making increased when clinicians used the knee osteoarthritis Option Grid.
Practice Implications: Tools designed to support collaboration and deliberation about treatment options lead to increased levels of shared decision making.

1. Introduction

Implementing shared decision making is a difficult challenge which has been attributed to a multitude of barriers, both practical and attitudinal [1,2]. By shared decision making, we mean a process where patients are supported by clinicians to deliberate about decisions and make choices that are well-aligned with their informed preferences [3]. There was hope that shared decision making could be achieved by introducing information to patients using decision aids [4]. There is good evidence that patient decision aids given ahead of clinical encounters lead to patients gaining knowledge, but there is little, if any, evidence that this approach has had a significant effect on the process of shared decision making [5,6]. However, tools that have been designed for use in the clinical encounter show more promise, becoming known by the term encounter tools [7]. This term is used to draw a distinction from tools that have been primarily designed to give patients information before they see clinicians, often called patient decision aids, and which we consider to be pre-encounter tools. Although there is consistent evidence that pre-encounter tools, which are usually information-rich, lead to increases in patient knowledge, there is much less evidence to show that they lead to changes in communication processes [5].

It remains the case that we do not have a substantive body of evidence from observational research that pre-encounter tools (patient decision aids), given to patients, lead to shared decision making [6]. Many reports conflate the dissemination of these pre-encounter tools with achieving shared decision making [8]. Yet, the literature reveals that very few researchers have evaluated the effect of patient decision aids on clinical interactions. Furthermore, if we divide the trials in the most recent Cochrane review [5] into

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those tools that have been designed for use in clinical encounter from those designed for use by patients before clinical encounters, an even clearer pattern emerges.

The studies that have evaluated the impact of these tools on observable communication processes have all been based on within-encounter tools. Of the 115 randomized controlled trials of 'patient decision aids' [5], four trials evaluated the effect of encounter tools on shared decision making, using direct observations of the clinical encounter [9–12]. Another Cochrane review of the findings of 39 studies of interventions for improving the adoption of shared decision making by health care professionals [13] identified the same four studies. We are aware of two other randomized trials of the effect of encounter tools on shared decision making. One was published since these systematic reviews were undertaken [14]. An earlier study of shared decision making, not included in the Cochrane reviews because the encounter tools were not categorized as 'decision aids', also evaluated communication process [15]. None of the other trials included in the Cochrane systematic review [5] assessed impact on clinical communication process using observer-based measures. Thus, most of this body of evidence only indirectly bears on interventions to improve shared decision making. Patient decision aids are better described today as supporting patient education; encounter tools are better described as supporting collaborative deliberation about healthcare choices. The theoretical basis for this hypothesis is based on the collaborative deliberation model and the use of tools to create conversations [3,16–18]. There is emerging quantitative and qualitative evidence that encounter tools are effective [19,20].

Option Grids are a form of encounter tool that clinicians have found to be useful during a previous implementation study [21]. The tools provide very brief information, organized as comparative answers to patient's 'frequently asked questions' about possible treatment options [22]. They are used to create collaborative conversations in clinical encounters. Although we have reports of many clinicians continuing to use the tools in daily work [21], further evidence of their effect is required. Hence, the aim of the trial was to investigate the effects of encounter tools called Option Grids in a new clinical setting, assessing their impact using observation-based and patient reported measures.

2. Method

2.1. Trial Design

We planned a stepped wedge trial in which six physiotherapists working in an interface clinic for musculoskeletal problems (see below) were instructed in how to use an Option Grid specifically developed for patients with osteoarthritis of the knee. The intervention was introduced sequentially in a stepped wedge design, using a timed order, based on the availability of the clinicians. This design is useful in situations where concurrent delivery of the intervention is not practical, as was the case in this busy service delivery setting which did not wish to undergo disruption to workloads by using group-based training [23]. This was also a single service setting, where clinician-to-clinician contamination is reduced by using this design. An evaluation was planned, comparing outcomes for patients participating in the intervention group with patients seen in the pre-intervention group. The intervention consisted of brief training about how to use the knee osteoarthritis Option Grid. This was given individually to each physiotherapist, according to their availability, and was approximately 20 min in duration. After the training, each physiotherapist used the tool with scheduled eligible patients who had consented for the study. The study proceeded as described in the protocol [24]. The intervention is described in Box 1 [35].

Box 1. Using the knee osteoarthritis Option Grid with patients (using TIDierR Checklist) [33].

The osteoarthritis Option Grid (see Appendix A)
1. **Name and Outline:** Option Grids are tools to support shared decision making [22]. To create Option Grids, information is collated from high quality systematic reviews and/or published high quality clinical practice guidelines. This information is then organized into a one-page tabular comparison of alternative potential treatments, described in relation to patients' frequently asked questions (FAQs). An expert editorial group is convened to develop the Option Grid (see editors listed). Iterative cycles of review and comment are used to refine the FAQs. Prior to publication, the osteoarthritis Option Grid was evaluated by patients, clinic staff and lay members of the charity Arthritis Care to ensure that the FAQs were relevant. After consensus is achieved, the tool was published on a publicly available website, which also describes the evidence synthesis and development processes.
1. **Rationale:** Tools that have been designed for collaborative use in clinical encounters have been shown to increase shared decision making, and we wanted to evaluate whether Option Grids could achieve this outcome.
2. **Who provided the Option Grids?** Physiotherapists working at the clinic and who were responsible for diagnosing and treating patients referred with knee pain.
4. **How and where were the Option Grids provided?** The six physiotherapists were allocated to a time-order, namely 1st to 6th, and each saw 6 consecutive, eligible patients before the training. After training in how to use the Option Grids, each physiotherapist, in the same time order, used the tools for 6 patients in the intervention group, in the usual clinic setting.
3. **Training and Tailoring:** Each physiotherapist was provided with individual training by the trial manager (KM) in how to use the Option Grid. The clinicians were asked to explain to patients that is was a tool to support them in choosing the correct treatment, and then to explain the tabular layout, (see Appendix A - Knee osteoarthritis Option Grid). They were then instructed to give the tool to the patient, along with a pen, and ask whether they would prefer to read the content themselves, or for the practitioner to explain the content. In both situations, the goal was to view and use the tool together. Finally, the physiotherapist was instructed to elicit questions from the patients and help them consider which treatment option best matched their preferences. If patients could not speak English, interpreters were enlisted so that they could assist the process. Each clinician was given copies of the tool to use when they saw patients in the intervention group.
6. **Modifications**: The physiotherapists were told that it was possible for them to modify the Option Grid, deleting inappropriate options where relevant.
4. **Fidelity**: The fidelity of the process was evaluated by observation, and by assessing a recording made of the clinical encounter.

2.2. Participants

Patients referred to an interface clinic with suspected or confirmed osteoarthritis of the knee were eligible, provided they were over the age of 18. Interpreters were sought when patients were not able to communicate in English. The physiotherapists at the interface clinic were informed about the trial objectives, and their consent to participate obtained and documented.

2.3. Study setting and patient recruitment

The study took place in Oldham, Greater Manchester, UK, where approximately 22.5% of the population in Oldham is non-white, compared to 14.3% across England. The employment rate is 58%, compared to 61% across England, and 29.6% of the population has no educational qualifications compared to 22.5% across England, and a significant percentage of patients who do not speak English as their first language, with 23% of the population from black, minority and ethnic groups compared to 15% in England [25,26].

The Pennine Musculoskeletal Clinic Limited holds a contract with the Oldham Clinical Commissioning Group (CCG), to provide services for rheumatology, orthopaedics and chronic musculoskeletal pain to the local population. This clinic receives all primary care referrals for musculoskeletal problems in the CCG area, to provide assessments, treatments, and, if necessary, referrals to other services, such as to orthopedic surgeons. Patients with knee problems were seen by physiotherapists with an extended scope of practice. The management options include: (i) advice, medication and physical therapy, (ii) joint injections, and (iii) further referral to assess the desirability of surgical intervention.

Clinic nurses and other allied health professionals identified patients by reading referral letters. A research nurse and clinic staff contacted potentially eligible patients. Patients who agreed to participate were sent an information pack comprising of an invitation letter, information sheet, and consent form to accompany their clinic appointment: data on age and gender was collected for these patients. Documented consent was obtained for patients who agreed to participate, and interpreters used to translate and discuss the study with patients who did not speak English.

2.4. Outcomes

The primary outcome of the study was the degree to which the use of the Option Grid led to an increase in shared decision making, as measured by the Observer OPTION instrument [27], the most widely used measure of shared decision making [28]. In this 12-item measure, raw scores (0–48) are transformed to be on a 0–100 scale. Each clinical encounter was audio-recorded and assessed by two independent assessors, trained to use the measure, and the mean of their two scores for each clinical encounter calculated. Patient's knowledge and 'readiness to decide' was also measured. These are two key factors in the measurement of informed patient preference—the core outcomes of shared decision making [29]. Patient's knowledge was measured using a Decision Quality Measure [30], adapted for use in this trial (see Appendix B), and completed immediately after their clinical encounter. The measure had 13 items, the first 5 items assessed knowledge (score range 0–5). The final 5 items assessed 'readiness to decide' (score range 0–5). Other items assessed the influences on patients' decisions. We asked patients to indicate what influenced their decision the most and we measured treatment alignment by comparing post-encounter treatment preference to the treatment identified at 3-month follow up (extracted from medical records). We measured patient health literacy using the REALM-R instrument [31], and pain severity using a Visual Analogue Scale [32]. Patient age, gender, postcode (to map Adjusted Index of Multiple Deprivation scores), and their highest educational attainment were collected from patient interviews and medical records. There were no changes to the proposed study outcomes.

2.5. Sample size

Based on previous studies, the anticipated mean score for Observer OPTION was 16.9 (0–100), with a standard deviation (SD) of 7.7 [28]. We estimated that the effect of the intervention would be to increase the mean by 50% to 25.4, and that the standard deviation would remain unaltered. The required sample was calculated to be 72 patients: with this sample the expected value of t was 4.66. Using an estimated intra-cluster correlation (ICC) of 0.22 gave a variance inflation factor of 2.1, and an expected value of t of 3.22, so the sample provided 90% power to detect a cluster-altered difference of this size. We planned that each of the 6 physiotherapists would see 6 patients in the pre-intervention group, and 6 in the intervention group.

Of the approximately 10,000 new patient referrals a year received by the Pennine Musculoskeletal Clinic, we estimated that roughly 12 patients per month would be referred with knee problems likely to be osteoarthritis. We estimated a 40% patient consent rate and calculated that we would have to approach a population of 180 eligible patients to obtain the required sample. A data collection period of 18 months was planned.

2.6. Statistical methods

Statistical analysis was undertaken using IBM SPSS Statistics 20 and MLwiN 2.28. The primary outcome of interest was the effect of the Option Grids in terms of facilitating shared decision making. Pre and post-intervention Observer OPTION scores were assessed using multilevel modeling, where the patient was the first level, and the physiotherapist was the second level. We calculated 'knowledge' and 'readiness to decide' scores, compared means in the pre-intervention and intervention groups, and assessed the most frequently reported influence on decision making in each group. Secondary analysis of the Decision Quality Measure, also using multilevel modeling, was used to compare whether the intervention improved knowledge and patients 'readiness to decide'. Data on age (measured in years), gender (male/female), educational level (from degree to no qualifications, five categories) employment status (employed full or part-time, retired, unemployed, seeking or not seeking work), main language spoken at home (English, Urdu, Bangla, other), the REALM-R score (6 and under considered low, 7 and over considered high) and pain severity score (continuous score) provided information on participant profiles. Age is an important epidemiological covariate and previous research has indicated a relationship between age and patients' desire to participate in decision making, so we investigated whether there were different relationships between age and outcome between the intervention and control groups. For the Observer OPTION outcome, we analyzed interactions between the following potential effect modifiers: REALM-R, age and deprivations scores. For the knowledge score, we analyzed the following effect modifiers: Observer OPTION, REALM-R and education. For the ability to make the right choice, we analyzed the following: Observer OPTION and REALM-R. We also assessed whether there were differences between the patients invited to those who consented and participated in the trial.

2.7. Ethical approval

The study protocol was approved by the South East Wales Research Ethics Committee (11/WA/0356). Written participant information about trial objectives and procedures was given to eligible patients, and informed consent documented.

3. Results

3.1. Participants

A total of 213 patients were identified: 78 consented, and the 72 allocated to the study, participated (for details see Fig. 1). There was no difference in the age and gender between those recruited and not recruited. The 72 patients allocated to the study had a mean age of 65.8 years, and, on average, were slightly older in the intervention group—for details see Table 1. In the sample recruited, 17% had no educational qualifications, and 51% had GSCE level education (or equivalent). Across all of Oldham, 30% have no educational qualifications compared to 23% across England [25]. The predominant ethnicity was white (British), 35/36 in pre-intervention group (97%), and 30/36 in intervention group (83%). For three encounters in the intervention group an interpreter was required to explain the Option Grid to the patient.

3.2. Observer OPTION scores

The mean Observer OPTION score was 29.4 (range 0–100, SD = 12.9) in the pre-intervention group and increased to 37.8 (SD 8.4) in the intervention group (95% confidence interval for the increase was 4.42 to 12.27). The ICC was 0.101 which implies less than anticipated clustering of physiotherapists on their Observer OPTION scores. Levels of deprivation nor health literacy had any impact on shared decision making levels measured. Differences between the raters' scores followed a Gaussian pattern. The OPTION scores of physiotherapists 5 and 6, who had the lowest Observer OPTION scores in the pre-intervention phase, gained the most points as a result of the intervention, gaining 12.7 and 11.3 points, respectively (see Fig. 2). We observed that although clinicians on average took 5 min and 20 s to cover the information in the Option Grid, this did not lead to longer encounters. The mean encounter duration when Option Grids were not used was 29 min 54 s (n = 36), compared to a mean duration of 29 min 26 s (n = 18, due to partial recordings) when Option Grids were used.

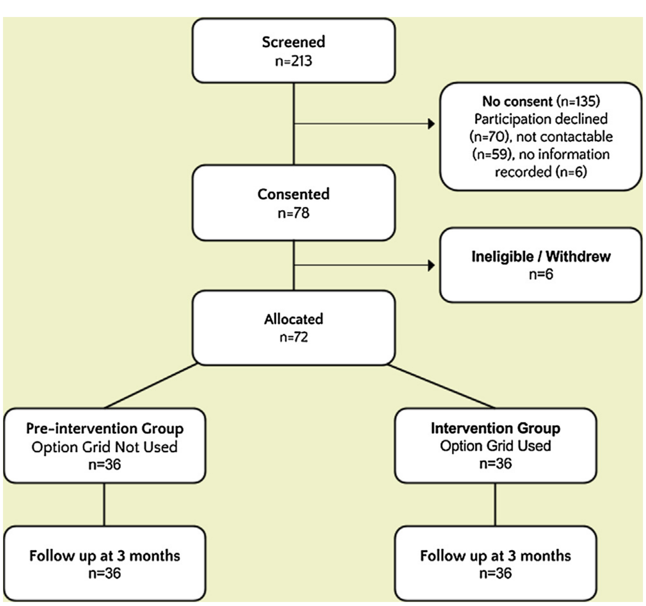

Fig. 1. Study participant flow.

Interpreters using the Option Grid took on average 4 min 36 s to cover the information in the tool (n = 3).

3.3. Decision quality measure and alignment

On average, knowledge evaluated by the Decision Quality Measure was 0.9 points in the intervention group (score range 0–5, 95% CI, 0.3 to 1.5), a difference that is statistically significant at the 5% level. There was no relationship between the knowledge score and the Observer OPTION score. Baseline patient education level had no effect on theses scores. The patients' 'readiness to decide' was 0.7 points higher in the intervention group (4.7 (SD 0.21) in intervention group; 3.9 (SD 2.04) pre-intervention; 95% CI, 0.2 to 1.3). Across both groups, the most frequently indicated influence on the decision was 'talking to the health professional'. In the intervention arm, the second most influential factor was 'reading the Option Grid given to me today'. There was no difference in treatment alignment between the pre-intervention and intervention group.

3.4. Effect modifiers

No statistically significant effect modifiers were observed, see Table 2.

4. Discussion and conclusion

4.1. Discussion

In this population of older patients, with lower than average health literacy, the use of the Option Grid by six physiotherapists increased the extent of observed shared decision making, led to increased patient knowledge about the condition, and increased their readiness to decide on the most appropriate treatment. Given the age profile and the stability of the population, it is unlikely that the patients exposed to Option Grids were systematically different to those not exposed, and so the change in shared decision making and knowledge can reasonably be attributed to the intervention. This gain in patient involvement was achieved without extending the duration of clinical encounters. It therefore seems that the clinicians were able to integrate the use of the tool without requiring more time to do so. Those clinicians who exhibited the least amount of shared decision making pre-intervention achieved the largest gain in their observed ability when using the encounter tool.

We recognise the limitations of the non-randomised stepped wedge design in that we were unable to control for some possible influences, both internal and external to the study setting. For instance, it is possible that the physiotherapists may have talked together as they were sequentially introduced to the encounter tools. If that was the case, this might have enhanced the implementation and impact of the Option Grid, so we view this as a possible positive influence, and one that could occur in typical settings. Alternatively, it is also possible that the contrast between pre-intervention and intervention groups could have been reduced, as physiotherapists who were awaiting their training gained skills in shared decision making by speaking to their colleagues.

We need to recognise that these encounters were based in the context of a referral-based service. These were patients referred from primary care to an interface clinic where approximately 30 min were scheduled for the encounters, and where the decision is not urgent. We observed a pattern of favourable influence of Option Grids on shared decision making in this situation, but we do not yet have data on their impact in shorter and unplanned clinical

Table 1
Participant characteristics.

		Arm				Total	
		Pre (*n* = 36)		Post (*n* = 36)			
Age		Mean	SD	Mean	SD	Mean	SD
		63.8	10.5	67.8	11.7	65.8	11.3
		n	%	*n*	%	*n*	%
Gender	Female	18	50	25	69	43	60
	Male	18	50	11	31	29	40
Adjusted index of multiple deprivation quintile	Least deprived	2	6	3	8	5	7
	Second least deprived	14	39	9	25	23	32
	Middle deprived	4	11	6	17	10	14
	Second most deprived	8	22	8	22	16	22
	Most deprived	8	22	10	28	18	25
Highest education level	Degree or equivalent (including post-graduate qualifications), other further education (diplomas, HND etc), A levels, vocational level 3'	11	31	10	28	21	29
	Trade apprenticeships, GCSE/O levels; other, level unknown (including foreign qualifications)	20	56	17	47	37	51
	No educational qualifications	4	11	8	22	12	17
Main language spoken	English	36	100	32	89	68	94
	Urdu	0	0	1	3	1	1
	Bangla	0	0	1	3	1	1
	Other	0	0	2	6	2	3

encounters, which are more typical of primary care settings, or in higher stakes contexts.

The study took place in a non-academic health service delivery setting where no changes were made in order to accommodate the interventions, save for briefly instructing the physiotherapists in the use of Option Grids. The patients recruited were similar in age and gender to all those deemed to be eligible for the study, and were typical of the population that is normally affected by osteoarthritis of the knee. The REALM-R score of participants was at a level that indicates below average health literacy.

The study provides evidence that brief tools that have been specifically designed for use in planned clinical encounters are able to support shared decision making, despite minimal training in their use. They lead to patients gaining knowledge and to increased readiness to make decisions, outcomes that have also been definitively shown for patients decision aids with more extensive information and that have been designed for use before clinical encounters [5]. In this study, we have evidence that the intervention supports shared decision making, that the use of Option Grids, after one instruction, has an effect on the interaction. Other studies have been able to demonstrate the effect of such encounter tools as well [19,20], but this is the first study to show that Option Grids have this effect, and that they can be used by clinicians in routine practice. The tools did not extend the duration of the encounter, although we recognize that these encounters are slightly longer than is typical for some service settings.

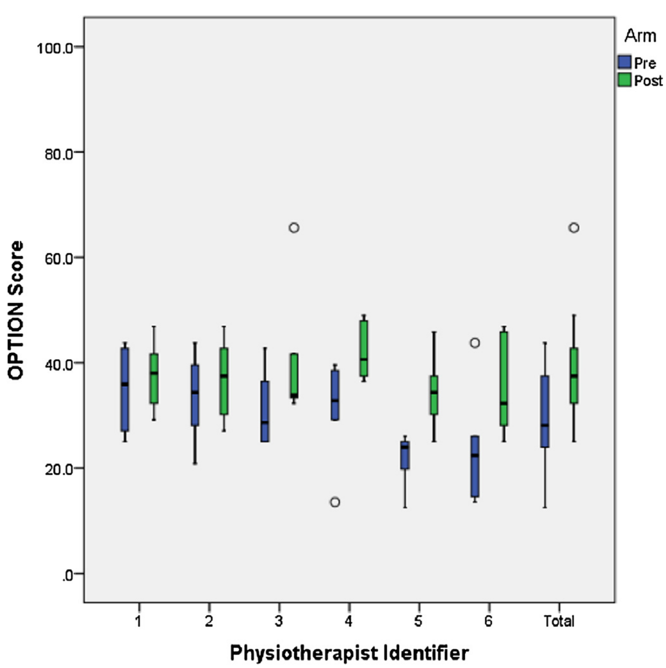

Fig. 2. Observer OPTION Scores Pre- and Post-use of knee osteoarthritis Option Grid.

4.2. Conclusion

When used collaboratively by patients and clinicians, tools that have been designed to fit into clinical encounters and which have high quality evidence about treatment options can support shared decision making, lead to gains in patient knowledge, and cause minimal disruption to existing routines.

4.3. Practice implications

As more policy emphasis is placed on patient centered care, and specifically on shared decision making, efforts will be required to find practical and efficient ways in which evidence can be presented in formats that patients and their clinicians find useful, feasible and might lead to better patient adherence to chosen treatments. The potential effect of tools such as Option Grids needs further investigation in other conditions, particularly around the best form of training, as well as in clinical settings such as primary care and where more emotionally-laden decisions are faced, such as considering cancer treatments or at the end of life.

Registration

Current controlled trials: ISRCTN 94871417.

Table 2
Interaction analysis of selected potential effect modifiers.

Outcome	Treatment group interaction		Interaction coefficient	Lower 95% confidence limit	Upper 95% confidence limit	*p*-value
Observer OPTION	REALM-R[a]		3.72	-4.73	12.18	0.39
	Age		0.31	-0.05	0.67	0.09
	Adjusted index of multiple deprivation[b]	2nd quintile	3.09	-13.84	20.02	0.72
		3rd quintile	11.11	-7.92	30.14	0.26
		4th quintile	-1.76	-19.42	15.90	0.85
		5th quintile	3.03	-14.20	20.26	0.73
Knowledge (Decision quality measure)	Observer OPTION		0.31	-0.05	0.67	0.09
	REALM-R[a]		-0.41	-1.67	0.85	0.52
	Education level[c]		1.03	-0.27	2.34	0.13
Readiness to decide (Decision quality measure)	Observer OPTION		-0.05	-0.11	0.01	0.12
	REALM-R[a]		0.39	-0.75	1.53	0.50

[a] Reference category is a score of 6 or less.
[b] Reference category is the least deprived quintile.
[c] Reference category is no qualifications.

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Appendix A.

The knee osteoarthritis Option Grid.

Appendix B.

Decision Quality Measure—13 items.

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